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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/683,846	10/10/2003	William Richard Heineman	0091830/0517360	2736

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FROST BROWN TODD, LLC
2200 PNC CENTER
201 E. FIFTH STREET
CINCINNATI, OH 45202

EXAMINER	
DIRAMIO, JACQUELINE A	

ART UNIT	PAPER NUMBER
1641	

NOTIFICATION DATE	DELIVERY MODE
07/26/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

dbell@fbtlaw.com
rgaunce@fbtlaw.com
aulmer@fbtlaw.com

Office Action Summary	Application No.	Applicant(s)
	10/683,846	HEINEMAN ET AL.
	Examiner	Art Unit
	Jacqueline DiRamio	1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 27 April 2007.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) 13-22 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-12 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 27, 2007 has been entered.

Status of the Claims

Applicant's amendments to claim 1 are acknowledged.

Currently, claims 1 – 12 are pending and under examination. Claims 13 – 22 are acknowledged as withdrawn as drawn to a non-elected invention.

Withdrawn Rejections

The previous rejections of the claims under 35 U.S.C. 112, first and second paragraph, are withdrawn in view of Applicant's amendments filed April 27, 2007.

All previous rejections of the claims under 35 U.S.C. 103(a) are withdrawn in view of Applicant's amendments and arguments filed April 27, 2007.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 – 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The invention is drawn to a method of detecting biological agents in finished water using molecular recognition elements.

(3) The relative skill of those in the art

The relative skill of the those in the art is high.

(2) The state of the prior art and (4) The predictability or unpredictability of the art

It is well known in the art that the binding between molecular recognition elements, such as antibodies and nucleic acids, and their corresponding biological targets, i.e. antigens and complementary nucleic acids, is highly specific. In particular, a specific antibody molecule is able to detect one molecule of a protein antigen out of more than 10^8 similar molecules. Therefore, by isolating an antibody with a known structure, the purified antibody can be effectively used to bind to and detect its known specific antigen (see Janeway et al. "Immunobiology, The Immune System in Health and Disease," 4th Ed. (1999) pg40-44). Similarly, nucleic acid sequences each contain a unique sequence with the property of binding specifically to a target compound or molecule, wherein methods such as SELEX (Systematic Evolution of Ligands by EXponential enrichment) can be utilized to determine specific nucleic acids that bind to a desired target compound (see US Patent no. 6,300,074). Thus, antibodies and nucleic acids can be efficiently used to bind to and detect various biological targets, as long as the structures of both the binding element, i.e. antibody or nucleic acid, and the biological target are known.

(5) The breadth of the claims

The method claims are drawn to a method of detecting biological agents in finished water using molecular recognition elements, wherein the biological agents have been altered by the effect of the finished water and the molecular recognition elements have been manipulated to recognize and specifically bind the altered biological agent.

(6) The amount of direction or guidance presented and (7) The presence or absence of working examples

The specification discusses the various treatments required in order to prepare finished water, wherein these treatments can result in an alteration of a biological target contained within the finished water sample. The alteration to the biological target, which can include the modification of a nucleic acid sequence or an epitope, can result in the biological agent becoming non-reactive or unable to bind to a known molecular recognition element (see specification paragraphs [0017]-[0021]). Therefore, in order to overcome these molecular recognition problems, Applicant discusses the manipulation of the molecular recognition elements in order for the molecular recognition elements to accurately recognize the modified targeted agent. The manipulations disclosed by Applicant include preparing new antibodies or nucleic acid sequences that have been manipulated to recognize the altered portions of the targeted agents (see paragraph [0030]). However, no guidance or working examples are given in order to enable one skilled in the art to practice the method of Applicant's invention. In particular, how does one determine if an alteration has occurred to the biological target, and if so, what type of alteration has occurred to the biological target in order to effectively prepare a new molecular recognition element, i.e. antibody or nucleic acid, that can accurately recognize the modified biological target. In order to conduct Applicant's claimed method, an assay must first be run in an attempt to detect a target biological agent in a sample of finished water using a molecular recognition element known to bind to the specific target biological agent. If the assay is conducted and no target biological agent is found to bind to the molecular recognition element, at this point, the user would assume either 1) no biological agent is present in the sample, or, according to Applicant's specification, 2) the biological agent is present but altered by the finished water. At this point, Applicant does not give any guidance or working examples as to how the alteration of the biological target is determined. The altered structure of the modified biological target must be known in order to manipulate the molecular recognition element to bind to the altered biological target. As discussed above in the state of the prior art, a purified antibody or nucleic acid sequence can be prepared in order to bind to a target compound, however, the structure of the target compound must be known. Therefore, it is unclear how exactly to practice the method of Applicant's invention if the alteration to the biological target is not specifically known or disclosed.

(8) The quantity of experimentation necessary

The unpredictability of the alteration that may occur to a target biological agent contained in a sample of finished water is extremely high. Therefore, because the instant specification provides very little guidance on what alterations will occur to a target agent one would be burdened with undue experimentation to practice the claimed invention.

Claims 1 – 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

In the instant case, the claims are drawn to a method of detecting biological agents in finished water using molecular recognition elements, wherein the biological agents have been altered by the effect of the finished water and the molecular recognition elements have been manipulated to recognize and specifically bind the altered biological agent. However, the specification does not provide ample written description for the type of alteration that occurs to the biological agent or how to manipulate the molecular recognition element to recognize the altered biological target.

The art indicates that the binding between molecular recognition elements, such as antibodies and nucleic acids, and their corresponding biological targets, i.e. antigens and complementary nucleic acids, is highly specific. In particular, a specific antibody molecule is able to detect one molecule of a protein antigen out of more than 10^8 similar molecules. Therefore, by isolating an antibody with a known structure, the purified antibody can be effectively used to bind to and detect its known specific antigen (see Janeway et al. "Immunobiology, The Immune System in Health and Disease," 4th Ed. (1999) pg40-44). Similarly, nucleic acid sequences each contain a unique sequence with the property of binding specifically to a target compound or molecule, wherein methods such as SELEX (Systematic Evolution of Ligands by EXponential enrichment) can be utilized to determine specific nucleic acids that bind to a desired target compound (see US Patent no. 6,300,074). Thus, antibodies and nucleic acids can be efficiently used to bind to and detect various biological targets, as long as the structures of both the binding element, i.e. antibody or nucleic acid, and the biological target are known.

Given the state of the art above, the specification does not provide ample written description for the claimed invention. The specification only discloses that an alteration can occur to the target biological agent, such as a modification to the nucleic acid sequence or to an epitope, wherein a molecular recognition element can be constructed in order to recognize the altered portions of the targeted agent (see paragraphs [0020]-[0021] and [0030]). However, the specification does not give any insight into how exactly the targeted agent is altered, such as the structure of the altered antigen/antibody or the modified nucleic acid sequence(s). The structure of the altered biological target must be known in order for one to effectively prepare a molecular recognition element, i.e, antibody or nucleic acid, that is manipulated to recognize and specifically bind to the altered biological agent. Accordingly, it is deemed that the specification fails to provide adequate written description for the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 – 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the phrase "wherein the targeted biological agent has been altered by the effect of the finished water," which is vague and indefinite because it is unclear how exactly the biological agent has been "altered."

Claim 1 also recites the phrase "one first molecular recognition element that is manipulated to recognize and specifically bind to the altered biological agent," which is vague and indefinite because it is unclear how exactly the first molecular recognition element is "manipulated" in order to recognize and bind to the altered biological agent.

Response to Arguments

Applicant's arguments filed April 27, 2007 have been fully considered but they are not persuasive. Applicant argues (see p6-7) that amended claim 1 is fully enabled by the specification, wherein paragraphs [0020] and [0046] of the specification provide methods for preparing modified recognition elements, particularly antibodies. Examiner agrees that Applicant's specification provides methods for preparing modified recognition elements, particularly antibodies, that can be used to practice Applicant's claimed invention. Further, it is well known in the art that antibodies, as well as nucleic acid sequences, can be prepared in order to bind to target compounds, however, the structure of the target compound must be known in order to effectively prepare an antibody or nucleic acid sequence that will recognize and bind to the target compound. Therefore, Applicant's argument (see p6) that the alteration of the target agent does not need to be specifically identified in order to provide a recognition element that recognizes the altered target agent is not considered persuasive. The unpredictability of the alteration that could occur to the target agent requires guidance by the Applicant as to how to prepare a manipulated recognition element when the altered structure or sequence of the target agent is unknown. For the reasons discussed above under 35 U.S.C. 112, first paragraph, Applicant's claimed invention is not considered to be fully enabled or described in order for one skilled in the art to make and/or use Applicant's claimed invention.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jackie DiRamio
Patent Examiner
Art Unit 1641

LONG V. LE 07/17/07
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600